UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to: All Actions	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

ASTRAZENECA'S OPPOSITION TO
PLAINTIFFS' MOTION TO AMEND THE VERDICT SHEET

Plaintiffs' proposed modifications of the Court's proposed verdict form (ECF No. 1333) misstate the law and would lead the Court into serious error. AstraZeneca respectfully submits that the proposed verdict form it filed yesterday (ECF No. 1337) is the appropriate one to use, and offers these specific responses to certain of Plaintiffs' requests to modify the draft verdict form the Court distributed on November 21. The question numbers referenced below refer to the numbering in the Court's November 21 form.

Question 1 (market power): Plaintiffs once again ask the Court to remove the "relevant antitrust market" language on the theory that "the jury can find that AstraZeneca exercised market power without considering the relevant market." ECF No. 1333 at 2. They made the same argument before the Court provided the first jury verdict form to the jury, and the Court rejected it. There is no reason for the Court to reconsider its ruling, and Plaintiffs provide none.

As Defendants noted in their submission regarding the first verdict form, in the First Circuit, "to prove a contract or combination in restraint of trade in violation of section 1 of the Sherman Act, the plaintiff must prove that the defendant had market power *in the relevant market* . . . ." *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 851 (1st Cir. 1985) (emphasis added); *see also Stop & Shop Supermarket v. Blue Cross & Blue Shield of R.I.*, 373 F.3d 57, 61 (1st Cir. 2004) ("As our prior decisions have explained, antitrust claims under section 1 of the Sherman

Act ordinarily require a burdensome multi-part showing [including] that the alleged agreement involved the exercise of power in a relevant economic market.").

This is a rule-of-reason case. *FTC v. Actavis*, 133 S. Ct. 2223 at 2237 (2013). As such, it requires the jury to analyze the agreement's actual effect on competition in a relevant market. *See CVD*, 769 F.2d at 851. Without defining the relevant market, the jury will lack meaningful context within which to assess the agreement's potential competitive effects. *See Stop & Shop Supermarket*, 373 F.3d at 69 ("It is not easy to think of a rule of reason analysis that does not depend on showing adverse effects on competition in a properly defined relevant market."); *see also, e.g.*, *Fraser v. Major League Soccer, L.L.C.*, 284 F.3d 47, 60–61 (1st Cir. 2002) (if Section 1 claim went to jury "it too would have been defeated by the jury's finding that the market alleged in the complaint had not been proved").

Contrary to Plaintiffs' assertions, this case does not qualify for the narrow exception for cases in which "proof of actual detrimental effects, such as a reduction of output, can obviate the need for an inquiry into market power." *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986). Plaintiffs identify no case in which any court in the First Circuit actually applies the *Indiana Federation* exception to exempt a plaintiff from showing harm in a relevant market (as opposed to simply noting the language in *Indiana Federation* without applying it), ECF No. 1333 at 1-2 & n.2, nor do they identify any supposed "direct evidence" of "actual detrimental effects" that could operate in this case to trigger such an exemption. Courts in reverse-payment cases have expressly rejected the notion that generic erosion curves and purportedly high margins (that do not take into account fixed costs such as research and development)—the types of "direct evidence" on which Plaintiffs here presumably would rely—constitute "direct evidence" that could enable a Plaintiff to avoid its burden to prove a relevant antitrust market.

See, e.g., *Geneva Pharms., v. Barr Labs.*, 386 F.3d 485, 500 (2d Cir. 2004) (finding "direct evidence" inconclusive without "any analysis of Barr's costs"); *In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 681–83 (D.N.J. 2005) ("Plaintiffs' approach, if applied beyond this case, would render most brand name pharmaceutical companies as *per se* monopolists prior to generic entry.").

Question 3 (anticompetitive effects and procompetitive justifications): Plaintiffs' request that Question 3 of the Court's proposed verdict form be amended should be denied for the same reasons the Court has already repeatedly rejected Plaintiffs' attempts to narrow the manner in which Defendants may articulate procompetitive justifications of the settlements.

Plaintiffs would have the jurors evaluate the "anticompetitive effects of the agreement(s)," but narrow the jurors' inquiry regarding procompetitive justifications to the alleged "payment(s)" alone. ECF No. 1333 at 2. That is not the law. Rather, "the inquiry mandated by the Rule of Reason is whether *the challenged agreement* is one that promotes competition or one that suppresses competition." *Nat'l Soc'y of Prof'l Eng'rs*, 435 U.S. 679, 691 (1978) (emphasis added). As *Actavis* itself recognized, an antitrust defendant must be allowed "show in the antitrust proceeding that *legitimate justifications are present*, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." 133 S. Ct. at 2237 (emphasis added).

Plaintiffs' purpose in seeking to amend question 3 is obvious: They wish to sever the provision of the agreement they regard as a "payment" to prevent the jury from considering that the agreements Plaintiffs challenge accomplish any number of procompetitive ends. Neither of the sources cited by Plaintiffs, *see* ECF No. 1333 at 3 n.7, supports the notion that the jury should be so restricted in its consideration of the procompetitive benefits of the agreements.

Plaintiffs' effort to narrow the jury's focus to procompetitive benefits of the alleged payment itself also assumes there would have been a so-called "payment-free" settlement that provided for an earlier licensed entry date. But there is no evidence in this record that such an alternative agreement would have been reached – rather, the record demonstrates that the parties would have continued to litigate had Ranbaxy insisted on a settlement that provided for an earlier entry date. There is no basis to demand that the jury assess the alleged "payment" without considering the numerous procompetitive benefits provided by the agreement that contains it so that the jury can weigh whether that outcome was more procompetitive than the alternative outcome that would have occurred – the parties continuing to litigate and AstraZeneca prevailing in the underlying litigation. The proper question for the jury is the one AstraZeneca proposed: "Was AstraZeneca's Nexium settlement with Ranbaxy unreasonably anticompetitive, that is, do the anticompetitive effects, if any, outweigh the procompetitive justifications."

Question 6 (causation): The Court's proposed verdict form asked: "Had it not been for either or both of these agreements, would a generic version of Nexium have come to market prior to May 27, 2014?" AstraZeneca agrees that the question should refer solely to the AstraZeneca-Ranbaxy agreement (and not "one or both of these agreements"), but disagrees with Plaintiffs' formulation otherwise.

First, to be consistent with the sole theory of liability that remains in this case and the Court's rulings, any question regarding a potential generic entrant should specify that it must be a *Teva* generic version of Nexium that allegedly was delayed to establish liability. Plaintiffs have never offered a theory that some other generic company would have done a deal with Ranbaxy or otherwise been in a position to obtain FDA approval to market a generic version of Nexium before May 27, 2014.

Second, as AstraZeneca proposed, the question whether a Teva generic version of Nexium would have come to market prior to May 27, 2014 requires answers to several questions that comprise Plaintiffs' remaining theory of liability. The jury should be required to answer the questions whether AstraZeneca and Ranbaxy would have agreed to an earlier license date, whether Ranbaxy would have relinquished exclusivity in favor of Teva, whether Teva would have obtained an earlier license date from AstraZeneca, and whether Teva would have obtained final approval from the FDA. *See* ECF No. 1337 (Questions 4, 5, and 6). All of these independent steps are critical parts of the causation chain that Plaintiffs bear the burden to prove.

Question 8 ("but for" date of entry): With respect to the Court's proposed Question 8, the Court should reject Plaintiffs' proposal that the question be revised to eliminate the requirement that Plaintiffs demonstrate the month and year when a generic version of Nexium would have come to market but for the AstraZeneca-Ranbaxy settlement agreement. ECF No. 1333 at 3.

First, Plaintiffs' requested change is an about-face. Addressing a nearly identically worded version of this question during the October 15 charge conference, Plaintiffs' counsel told the Court: "it's correct, you know, 'When [would] they first have come to the market?' That is correct." 10/15/14 Tr. at 12. Plaintiffs changed their mind about the "correct[ness]" of this formulation only when they recognized their failure to provide the jury with any legitimate basis on which to find such a but-for entry date.

Second, the particular date of entry clearly is not simply a "damages issue," as Plaintiffs contend. ECF No. 1333 at 3. Rather, the question of when (if ever) Teva's generic version of Nexium would come to market but for the Ranbaxy settlement is a question of *causation* and *fact of injury*—issues on which Plaintiffs most certainly bear the burden of proof. This is easily

demonstrated by considering the tortured chain of events Plaintiffs must prove to establish causation pursuant to the sole remaining theory of liability in this case. To prevail, Plaintiffs must demonstrate that, absent the alleged large and unjustified payment made to Ranbaxy:

(a) AstraZeneca would have agreed to a settlement agreement with Ranbaxy that licensed Ranbaxy for an entry date prior to May 27, 2014;

(b) AstraZeneca would have entered into a settlement agreement with Teva that would have provided a license to Teva for the same earlier entry date that was provided to Ranbaxy;

(c) prior to May 27, 2014, Ranbaxy and Teva would have entered into an agreement that provided for Ranbaxy to relinquish its 180 day Hatch Waxman exclusivity;

(d) prior to May 27, 2014, Ranbaxy would have, in fact, relinquished its Hatch-Waxman exclusivity;

(e) Teva would have obtained final FDA approval to sell its generic Nexium product after Ranbaxy had relinquished its exclusivity but before May 27, 2014; and

(f) Teva would have launched its generic Nexium product after that earlier licensed entry date but before May 27, 2014.

Plaintiffs' failure to prove precisely when Teva would have brought a generic version of Nexium to market makes it impossible to demonstrate that any purported delay resulted from AstraZeneca's agreement with Ranbaxy rather than Teva's inability to obtain timely FDA approval, Ranbaxy's refusal to relinquish its exclusivity for reasons independent of its agreement with AstraZeneca, or Teva's inability to produce its generic version Nexium in sufficient quantity to enter the market.

Thus, Plaintiffs' effort to characterize the Teva "but for" entry date as a "damages issue" is in reality an effort to avoid demonstrating causation and fact of injury. None of the cases they cite, ECF No. 1333 at 3-4 n.11, support that effort. Each one of those cases address the quantum of evidence Plaintiffs must adduce to prove actual damages *after the fact of liability has been*

established. They contradict Plaintiffs' position here because they affirm that plaintiffs bear the full burden of proving causation and injury in fact.[1]

Finally, Plaintiffs' proposal makes no practical sense and indeed would be grossly inefficient because it would require a Phase II damages jury to hear again all of the evidence presented in this trial regarding the entry date of generic Nexium in a world without the challenged settlement. This jury has heard the evidence and is competent to answer the question of when, if ever, Teva's generic Nexium product would have come to market but for the challenged settlement. It is of course also possible that the jury's answer will obviate the need for a Phase II trial on damages altogether. If, for example, this jury determines that a Teva product would not come to market until after May 27, 2014, then there would be no causation, no injury-in-fact, and no need for a damages phase at all. There is no legal basis to lessen Plaintiffs' burden of proof on this critical issue.

Dated: December 2, 2014

Respectfully submitted,

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[1] "It is a requirement that an antitrust plaintiff must prove that his damages were caused by the *unlawful* acts of the defendant." *MCI Commc'ns v. AT&T Co.*, 708 F.2d 1081 (7th Cir. 1983); *see also, e.g.*, *BCS Servs., Inc. v. Heartwood SS, LLC*, 637 F.3d 750, 759 (7th Cir. 2011) ("*If a trier of fact finds causation* . . . the only remaining issue is the amount of damages to be awarded. . . . *Once the plaintiff proves injury*, broad latitude is allowed in quantifying damages." (emphases added)); *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 533 (6th Cir. 2008) ("*Once liability is established*, therefore, a plaintiff's proof of damages is evaluated under a more lenient standard (emphasis added)); *Matrix Warehouse v. Daimler-Benz Aktiengesellschaft*, 828 F.2d 1033, 1044 (4th Cir. 1987) ("[O]ur decisions also recognize that the antitrust *plaintiff must demonstrate a causal connection* between the defendant's *violation* and the damages claimed." (emphasis added)).

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CERTIFICATE OF SERVICE

I, James H. Weingarten, hereby certify that this document was electronically filed and served using the Court's ECF system on December 2, 2014.

/s/ James H. Weingarten
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